

## REMARKS

### Amendment to the Specification

A substitute specification in compliance with 37 CFR 1.52 and 1.121(b)(3) has been submitted. Pursuant to 37 CFR §1.121(b)(3), Applicant hereby introduces an amendment to specification, other than the claims, by submitting (i) instructions to replace the specification, and (ii) a marked-up and a clean copies of the substitute specification in compliance with 37 CFR §1.125(b) and (c).

Applicant amended the specification as follows:

(1) The term “carboxilic acid” has been replaced with the term “carbonic acid” throughout the Application.

The German term “Kohlensäure”, used in the International Application PCT/EP2004/000488, published in German as WO 2004/065425, was incorrectly translated as “carboxylic acid” rather than “carbonic acid”. Applicant submits that this error is obvious to one of ordinary skill in the art. To further support this assertion, Applicant submits herewith Exhibit A. Exhibit A is a printout of a page from a German-English online dictionary available at URL <http://dict.leo.org/ende?lp=ende&p=KO6ek.&search=Kohlens%E4ure> (last accessed on July 18, 2008). Exhibit A indicates that the correct translation of the German term “Kohlensäure” into English is “carbonic acid”.

(2) Section headings have been added

(3) Summary section has been added by moving the paragraph at page 1, starting on line 17, of the substitute specification to the Summary section to conform to the U.S. practice.

(4) Abstract has been added.

(5) The first page header has been replaced and the name of the inventor and the attorney’s docket number have been added to the first page.

### Claim Status

Claims 1 through 30 were previously cancelled by the Preliminary Amendment filed on July 20, 2005. By the present Amendment, Claims 31 through 60 are cancelled and new Claims 61 through 79 are added.

### Claim Amendments

In new Claims 61 through 79, the term “carboxylic acid diester” has been replaced by the term “carbonic acid diester”. As explained above, page 2, paragraph 3 of this Amendment, the term “carbonic acid diester” is the correct translation of the German term “Kohlensäurediester”.

New Claim 61 is drawn to the subject matter of Claim 31, as presented in the Preliminary Amendment filed on July 20, 2005, further adding the limitations of Claims 32 and 38, as presented in the Preliminary Amendment. In new Claim 61, the term “polysaccharides or polysaccharides derivatives” has been replaced by the term “hydroxyethyl starch (HES)”. Applicant notes that the term “hydroxyethyl starch” is within the scope of Claims 32 and 38. Additionally, the limitations of Claim 38 have been incorporated in new Claim 61 (i.e. “a mean molecular weight  $M_w$  in the range 2,000<sup>1</sup>-300,000 dalton, a degree of substitution  $MS$  between 0.1 and 0.8, and a C2/C6 ratio of the substituents on the carbon atoms C2 and C6 of the anhydroglucoses between 2 and 15”). Support for this amendment has been found in Claims 31, 32 and 38 as presented by the Preliminary Amendment and additionally, on pages 10, lines 24 through 31 and on page 11, lines 1 and 2 in the substitute specification.

New Claim 62 is drawn to the subject matter of Claim 39, as presented in the Preliminary Amendment filed on July 20, 2005. Support is found in Claim 39, as presented in the Preliminary Amendment.

New Claim 63 is drawn to the subject matter of Claim 40, as presented in the Preliminary Amendment filed on July 20, 2005. Support is found in Claim 40, as presented in the Preliminary Amendment.

New Claim 64 is drawn to the subject matter of Claim 41, as presented in the Preliminary Amendment filed on July 20, 2005. Support is found in Claim 41, as presented in the Preliminary Amendment.

New Claim 65 is drawn to the subject matter of Claim 42, as presented in the Preliminary Amendment filed on July 20, 2005. Support is found in Claim 42, as presented in the Preliminary Amendment.

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<sup>1</sup> An obvious typographical error 2-300 000 dalton, as presented in Claim 38, has been corrected to 2000-300 000. Further support for this correction can be found on page 5, lines 15 through 17 in the substitute specification.

New Claim 66 is drawn to the subject matter of Claim 43, as presented in the Preliminary Amendment filed on July 20, 2005. Support is found in Claim 43, as presented in the Preliminary Amendment.

New Claim 67 is drawn to the subject matter of Claim 44, as presented in the Preliminary Amendment filed on July 20, 2005. Support is found in Claim 44, as presented in the Preliminary Amendment.

New Claim 68 is drawn to the subject matter of Claim 45, as presented in the Preliminary Amendment filed on July 20, 2005. Support is found in Claim 45, as presented in the Preliminary Amendment.

New Claim 69 is drawn to the subject matter of Claim 49, as presented in the Preliminary Amendment filed on July 20, 2005. Support is found in Claim 49, as presented in the Preliminary Amendment.

New Claim 70 is drawn to the subject matter of Claim 50, as presented in the Preliminary Amendment filed on July 20, 2005, further adding the limitations of Claim 38, as presented in the Preliminary Amendment filed on July 20, 2005. Support is found in Claims 50 and 38, as presented in the Preliminary Amendment and additionally on pages 10, lines 24 through 31 and on page 11, lines 1 and 2 in the substitute specification.

New Claim 71 is drawn to the subject matter of Claim 51, as presented in the Preliminary Amendment filed on July 20, 2005. Support is found in Claim 51, as presented in the Preliminary Amendment.

New Claim 72 is drawn to the subject matter of Claim 52, as presented in the Preliminary Amendment filed on July 20, 2005. Support is found in Claim 52, as presented in the Preliminary Amendment.

New Claim 73 is drawn to the subject matter of Claim 53, as presented in the Preliminary Amendment filed on July 20, 2005. Support is found in Claim 53, as presented in the Preliminary Amendment.

New Claim 74 is drawn to the subject matter of Claim 55, as presented in the Preliminary Amendment filed on July 20, 2005. Support is found in Claim 55, as presented in the Preliminary Amendment.

New Claim 75 is drawn to the subject matter of Claim 56, as presented in the Preliminary Amendment filed on July 20, 2005. Support is found in Claim 56, as presented in the Preliminary Amendment.

New Claim 76 is drawn to the subject matter of Claim 57, as presented in the Preliminary Amendment filed on July 20, 2005. Support is found in the Claim 57, as presented in the Preliminary Amendment.

New Claim 77 is drawn to the subject matter of Claim 58, as presented in the Preliminary Amendment filed on July 20, 2005. Support is found in Claim 58, as presented in the Preliminary Amendment.

New Claim 78 is drawn to the subject matter of Claim 59, as presented in the Preliminary Amendment filed on July 20, 2005. Support is found in Claim 59, as presented in the Preliminary Amendment.

New Claim 79 is drawn to the subject matter of Claim 60, as presented in the Preliminary Amendment filed on July 20, 2005. Support is found in Claim 60, as presented in the Preliminary Amendment.<sup>2</sup>

#### Election/Restriction

In the Office Action mailed on April 22, 2008, the Examiner required that Applicant selects one of the five inventions for the prosecution on merits. The Examiner restricted the claims to the following five groups:

Group I Claims 31-43 drawn to aprotic-solvent soluble carboxylic acid diester of a polysaccharide or polysaccharides derivatives.

Group II Claim 44, drawn to a solid comprising a carboxylic acid diester of a polysaccharide.

Group III Claims 45-49 drawn to a solution comprising a carboxylic acid diester of a polysaccharide.

Group IV Claims 50-54 drawn to a method for preparing a carboxylic diester of a polysaccharide.

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<sup>2</sup> Applicant note that the correct dependence in Claim 60, as presented in the Preliminary Amendment filed on July 20, 2005, should be on Claim 55 instead of Claim 25.

Group V Claims 55-60 drawn to a method for producing a pharmaceutically active substance and a pharmaceutically active product.

Applicant traverses the restriction of Groups I, II, III, IV and V and requests rejoinder.

The Examiner stated that the inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical feature under PCT Rule 13.2. The Examiner stated that the inventions of Groups I-V do not relate to a single general inventive concept because the special technical feature, “a carboxylic acid diester of polysaccharides or polysaccharide derivatives”, lacks novelty over U.S. Patent No. 2, 868, 781 (“Gaertner”).

New Claims 61-79 have been added by the instant amendment. New Claims 61-66 correspond to Group I, new Claim 67 corresponds to Group II, new Claims 68-69 correspond to Group III, new Claims 70-73 correspond to Group IV, and new Claims 75-79 correspond to Group V.

Applicant submits that the new claims introduced by the instant claim amendment render the restriction requirement moot. Indeed, in the amended claims the corresponding “special technical feature” is a *carbonic acid diester* of hydroxyethyl starch (HES). Rule 13.2 defines the “special technical feature” as a technical feature that defines *a contribution which the invention, considered as a whole, makes over the prior art*. Under the definition of the “special technical feature” provided by PCT Rule 13.2, in order to show that Groups I-V lack unity, evidence such as a prior art reference, showing that this feature does not define a contribution over the prior art must be provided. Since Gaertner discloses *carboxylic acid diester*, rather than *carbonic acid diester*, its teachings are inapplicable to new Claims 61-79. As such, there is no prior art reference on record that teaches the special technical feature of Claims 61-79. Accordingly, Applicant requests withdrawal of the instant restriction requirement.

However, for the sole purpose of being in compliance with the requirement of 37 C.F.R. §1.499, Applicant hereby provisionally selects the invention of Claims 61-66, which correspond to the claims of Group I as originally defined. This is a provisional election pending the outcome of the traversal of the instant restriction. Applicant reserves the right to file a continuing application or take such other appropriate action as deemed necessary to protect the non-elected

inventions. Applicant does not hereby abandon or waive any rights in the non-elected inventions.

Reconsideration and withdrawal of the restriction are respectfully requested.

**CONCLUSION**

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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